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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/802,110	03/07/2001	James Leushner	VGEN.P-058-2	5580

21121 7590 01/13/2003
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EXAMINER

WILDER, CYNTHIA B

ART UNIT PAPER NUMBER

1637

DATE MAILED: 01/13/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/802,110

Applicant(s)
LEUSHNER et al.

Examiner
Cynthia B Wilder

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 13, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-36 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election in Paper No. 15 is acknowledged. However, the election is deemed moot in view of Applicant's preliminary amendment canceling claim 1-12 and adding new claims 13-36. An action on the merit appears below for claims 13-36.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

3. Claims 13, 15, 16, 27, 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claim 13 is grammatically incorrect at "a one or more". It is suggested deleting "a".

(b) Claims 15, 16, 27 and 28 are grammatically incorrect at "is form sequencing". It is suggested changing "form to "for".

(c) Claims 15 and 27 are confusing because the claims appear to be redundant in nature without clearly further limiting the prior claim. It is suggested amending the claims to recite "The kit of claim 14 for sequencing one or more DNA regions from a genomic sample, wherein the kit comprises the pair of primers for binding to the sense and antisense strands of the genomic sample."

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or some other language as supported by the specification as originally filed. The same changes should be made to claim 27 for clarity.

(d) Claims 16 and 28 are confusing because the claims appear to be redundant in nature without clearly further limiting the prior claim. It is suggested amending the claim to recite "The kit of claim 14 for sequencing one or more DNA regions from a selected microorganism, wherein the kit comprises the pair of primers for binding to the sense and antisense strands of the microorganism." or some other language as supported by the specification as originally filed. The same changes should be made to claim 28 for clarity.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 13, 20, 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-8 of U.S. Patent No. 5, 830,657. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are drawn to a kit for sequencing multiple DNA regions. The claims only slightly differ in scope one from the other. For example, the claims 13-36 of instant invention are drawn to a kit for sequencing one or more DNA regions from a genomic DNA sample or a microorganism whereas the claims 6-8 are drawn to a method and kit for sequencing a plurality of DNA regions from a genomic DNA sample. The claims of the instant invention differ from the claims of Patent '657 in that the kit of the instant invention specifies sequencing multiple DNA regions from a genomic DNA sample and/or a microorganism whereas the kit of claims 6-8 of Patent '657 specifies sequencing multiple DNA regions from a genomic DNA sample. The difference between the claims of the instant invention and claims of Patent '657 are not patentably distinct because a genomic DNA sample may encompass DNA from a microorganism or non-microorganism. The slight difference in scope does not equate to a patentable distinction.

6. Claims 13-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No.6,214,555. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to kit comprising a pair of primers which binds to the sense and antisense strands, and flank a DNA region within a genomic or microorganism DNA, a mixture of four deoxynucleotide triphosphates and at least dideoxynucleotide triphosphate corresponding to one of the four deoxynucleotide triphosphates, wherein the dideoxynucleotide triphosphate is present in a mole ratio to the corresponding deoxynucleotide triphosphates of from 1:50 to 1:1000 and a polymerase which incorporates dideoxynucleotides into an extending nucleic acid polymers at a rate which is no less than 0.4 times the rate of incorporation of deoxynucleotides. The claims of the instant invention differs from claims 1-12 of the patent '555 in that the claims 1-12 of patent '555 are limited to a kit and composition for detecting a genomic target microorganism whereas the claims of the instant invention encompass a kit for sequencing one or more DNA regions from a genomic DNA sample and/or microorganism. The slight difference in scope does not equate to a patentable distinction between the inventions.

7. Claims 13-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4-5 of U.S. Patent No. 6,083,699. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass determining a target DNA regions in a sample using a set oligonucleotide primers which binds to the sense and antisense strands of the target nucleic acid at a location flanking the target region and a DNA polymerase which incorporates dideoxynucleotides into an extending nucleic acid polymer at a rate which is no less than 0.4 times the rate of incorporation of

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deoxynucleotide. The claims of Patent '699 differs from the claims of the instant invention in that the claims of Patent '699 are not in the form of a kit as recited in the claims of the instant invention. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have been motivated to provide the components of claims 1-2 and 4-5 of Patent '699 in the form of a kit for the obvious benefits of ease and convenience of practicing to the investigator.

Closest Prior art

8. The closest prior art, Tabor et al. (4,963,020, October 1990) teach a kit for sequencing DNA comprising a first container comprising a polymerase, a second container comprising a chain terminating agent wherein the chain terminating agent is dideoxynucleoside triphosphate, and a compound comprising a manganese ion, the kit further comprising a deoxyribonucleoside triphosphate and a chelator.

Hornes (WO 93/08305, April 1993) teaches a kit for sequencing of both strands of double stranded DNA comprising a pair of primers, the first of which is provided with a functional group for subsequent attachment to a first solid support, and the second of which is provided with a different functional grouping permitting attachment to a second solid support, one or more polymerases; and one or more appropriate buffers; dideoxynucleotides ddT, ddA, ddC and ddG; dideoxynucleotides or an oligonucleotide, each carrying, or adapted to carry a label.

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Conclusion

9. No claims are allowed.

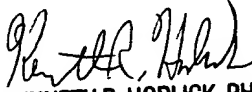
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's Patent Analyst, Monica Graves at (703) 305-3002 or Group's receptionist at (703) 308-0196.

Cynthia B. Wilder, Ph.D.

January 2, 2003


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

1/8/03